IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Scott Cordray SERIAL NO. 10/018,953 FILED: December 21, 2001	ATTY DKT NO. P-120873.1(PCT)(US)
TITLE: NASAL SPRAY HAVING DEAD SEA SALT	
TO: OFFICE OF PETITIONS **Commissioner of Patents and Trademarks** **Washington, D.C. 20231**	

Commissioner of Patents and Trademarks
Washington, D.C. 20231

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNAVOIDABLY UNDER 37 CFR 1.137(a)

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

Although Applicants believe no further fee is due in this case, due to the explanation below and the documents which are attached, a petition fee of $55.00 (37 CFR 1.17(l))(small entity) is enclosed. The U.S. Patent and Trademark Office is also hereby authorized to charge any further fees, or discrepancies in fees required, to Deposit Account **07-2400**.

The above-identified application became abandoned for failure to file a timely and proper reply to the Notice of Missing Requirements dated February 22, 2002 (copy enclosed) which was never received in our offices. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus any extensions of time actually obtained.

An adequate showing of the cause of the delay, and that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition under 37 CFR 1.137(a) was unavoidable, is explained herein. It basically is because the notice of missing requirements and latest notice of abandonment were both sent to a completely wrong address (300 Convent Street, Suite 1650, San Antonio, TX 78205).

This application was filed on December 21, 2001 and is based on PCT Serial No. PCT/US00/18012 which was filed on June 30, 2000 and has a priority date of June 30, 1999. On July 5, 2001 in parent PCT application Serial No. PCT/US00/18012 a "Withdrawal of Head, Johnson & Kachigian as Attorneys of Record" and "Change of Address for Daniel S. Hodgins, Attorney of Record" was filed. A copy of those documents along with the Express Mail Label is

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02 FC:2251 55.00 OP

enclosed. In reviewing the parent application PCT/US00/18012, the "Change of Address and Withdrawal" was never entered or acknowledged by the U.S. Patent or PCT Receiving Office.

On December 21, 2001, the PCT application was filed in the U.S. National Phase and is now Serial No. 10/018,953. A copy of the documents and check, along with the PTO stamped postcard receipt is attached herewith. The address change again was **NOT** acknowledged and since it has never been properly entered into the parent application PCT/US00/18012 it was not carried over from that application.

On December 3, 2002 Mrs. Kathy Short of the U.S. Patent Office was contacted and it was discovered that the address change had still not been entered for the application. Accordingly, another change of address was faxed to her along with a cover letter on December 3, 2002 in Serial No. 10/108,953. A copy of the facsimile transmission receipt, the letter and change of address is attached.

On January 21, 2003, we filed a Status Inquiry for which a reply has never been received from the U.S. Patent and Trademark Office. A copy of the Status Inquiry and the PTO stamped postcard receipt is attached.

On February 20, 2003, my secretary received a telephone call from Pat Booker asking if this address, Jackson Walker, LLP, 112 East Pecan St., Ste. 2100, San Antonio, TX was the correct address for the attorney of record, Daniel Hodgins. My secretary confirmed that indeed this was the correct address. Ms. Booker stated that the address change was never recorded and that the application was now abandoned. At that time, all of the above paperwork was faxed over to Ms. Booker's office but not matched up with the file. When my secretary placed several more telephone calls to several employees (a page of notes is attached), it was discovered that the application file had been sent to the Warehouse on the same date as the facsimile and telephone calls and the proof of address changes that were faxed over on February 20, 2003 were not entered at that time.

On March 10, 2003, my secretary contacted Dan Stemmes of the U.S. Patent Office and again explained the situation. Mr. Stemmes retrieved the patent application file and noted that all the documents (including the February 20, 2003 fax of proof of address change) were indeed in the file, but the address change had again not been entered. Accordingly, on March 10, 2003, the correct address was finally entered into this application number 10/018,953, but not in the parent PCT case PCT/US00/18012. Confirmation was transmitted to Daniel Hodgins, the attorney of record..

The correct address and change of addresses was never timely entered into the application and the U.S. Patent and Trademark Office abandoned the application on November 15, 2002 (a copy of the notice is attached). The Notice of Abandonment and Notice of Missing Requirements were faxed to our offices on March 10, 2003, along with confirmation that the address has been updated on March 10, 2003, although the initial address change was filed over three years ago, or in 2000, another one in December of 2002 and finally proof of those filings sent to the PTO by facsimile on February 20, 2003 (placed in the file but not entered).

Accordingly, since proper changes of address have been filed and followed up on by the attorney of record, Daniel Hodgins over the last three years, but the change of address has never been formally entered, Applicants petition the Patent Office to reinstate the above-identified patent application and enter the accompanying response to the Notice of Missing Requirements.

A list of these documents is attached in chronological order as proof on Applicant's part of trying to get the address for this application updated:

1. March 10, 2003: Confirmation fax from Dan Stammer indicating the address has been updated and enclosing copies of the Notice of Abandonment and Notice of Missing Requirements was not received in our offices.

   A. Notice of Abandonment (misaddressed).
   B. Notice of Missing Requirements (wrong address).

2. Copies of notes of telephone calls made and not responded to by the PTO regarding the change of address, including a typed list of those names.

3. February 20, 2003: Fax to Pat Booker's Office of copies of postcard receipt and change of address information that had been filed but not entered (placed in the file, the file sent to the warehouse and the address change still not entered).

4. January 21, 2003: Status Inquiry and stamped PTO postcard receipt, which to this date has not been responded to.

5. December 3, 2002: Copy of Change of Address, Facsimile Receipt Transmission and Letter to Kathy Short of the U.S. PTO, faxed to the PTO as a second Notice of Change of Address.

6. Copy of the Application Serial No. 10/108,953, the check, and Postcard Receipt as filed on December 21, 2001.

7. July 5, 2001: Copy of "Withdrawal of Head, Johnson & Kachigian as attorneys of record and Change of Address" for Daniel Hodgins as filed in parent PCT application Serial No. PCT/US00/18012 which to this date has not been entered.

8. January 31, 2002: Copy of first page of Transmittal of Preliminary Exam report, as an example that the Change of Address filed in PCT/US00/18012 on July 5, 2001 has *still* not been entered with the incorrect address highlighted on the first page as proof.

9. Proposed response to the Notice of Missing Requirements.

10. Inventor's Declaration.

11. A Petition Fee of $55.00.

12. A check for the Notice of Missing Requirements Surcharge Fee of $65.00.

Respectfully submitted,
JACKSON WALKER L.L.P.

Daniel D. Hodgins
Reg. No. 31,026
112 E. Pecan Street, Suite 2100
San Antonio, Texas 78205
(210) 978-7700 (phone)
(210) 978-7790 (fax)
Attorneys for Applicant

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited on the date shown below with the United States Postal Service, with sufficient postage as First Class Mail (37 CFR 1.8(a)), in an envelope addressed to Honorable Commissioner of Patents, Washington, D.C. 20231.

Date: March 20, 2003

Michelle Grosche

Michelle Grosche

12. A check for the Notice of Missing Requirements Surcharge Fee of $65.00.

Respectfully submitted,
JACKSON WALKER L.L.P.

Daniel S. Hodgins
Reg. No. 31,026
112 E. Pecan Street, Suite 2100
San Antonio, Texas 78205
(210) 978-7700 (phone)
(210) 978-7790 (fax)
Attorneys for Applicant

CERTIFICATE OF MAILING

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Date: March 20, 2003

Michelle Grosche

Michelle Grosche

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Scott Cordray SERIAL NO. 10/018,953 FILED: December 21, 2001	ATTY DKT NO. P-120873.1(PCT)(US) GROUP NO.: Unassigned
TITLE: NASAL SPRAY HAVING DEAD SEAT SALT	
TO: Commissioner of Patents and Trademarks Washington, D.C. 20231	

COMPLETION OF FILING REQUIREMENTS
(RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

This replies to the Notification of Missing Requirements of Application mailed February 22, 2002. The following documents are enclosed:

1. A copy of the Notification of Missing Requirements of Application.

2. Declaration:
   [X] No original declaration or oath was filed, and enclosed is the original declaration or oath for this application.
   [ ] The original declaration or oath which was filed was determined to be defective. A new original oath or declaration is attached.

3. Fees:
   [ ] Late payment of filing fee. ($65.00 Large Entity)

   and/or

   [X] Late filing of original declaration or oath (37 CFR 1.16(e)) ($65.00; Small entity)

4. Other:

Respectfully submitted,

JACKSON WALKER, LLP

04/02/2003 GFREY1 00000070 10018953
01 FC:2617 65.00 OP

By _____
Daniel S. Hodgins
Reg. No. 31,026

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited on the date shown below with the United States Postal Service in an envelope addressed to the "Commissioner of Patents and Trademarks, Washington, D.C. 20231", as follows:

37 CFR 1.8(a)	37 CFR 1.10
[ ] With sufficient postage as First Class Mail. Date: 3/20, 2003.	[ ] As "Express Mail Post Office to Addressee", Mailing Label No. _____. Date: _____, 20___.

Michelle Grosche
Printed Name of Person Mailing Paper or Fee

Michelle Grosche
Signature of Person Mailing Paper or Fee

3333720v1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTOR: Scott Cordray TITLE: NASAL SPRAY HAVING DEAD SEA SALT	ATTY DKT NO.P-120873.01 (PCT)(US)

COMBINED DECLARATION AND POWER OF ATTORNEY
(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

[X] original
[ ] design
[ ] supplemental

NOTE: If the declaration is for an International Application being filed as a divisional, continuation, or continuation-in-part application, do not check next item; check appropriate one of last three items.

[X] national stage of PCT

NOTE: If one of the following three items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION or CIP.

[ ] divisional
[ ] continuation
[ ] continuation-in-part

INVENTORSHIP IDENTIFICATION

WARNING: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor *(if only one name is listed below)* or an original, first and joint inventor *(if plural names are listed below)* of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION:
NASAL SPRAY HAVING DEAD SEA SALT

SPECIFICATION IDENTIFICATION

the specification of which: *(complete (a), (b) or (c))*

(a) [ ] is attached hereto
(b) [X] was filed on December 21, 2001 as Serial No. 10/018,953 or

[ ] Express Mail No. _____, as Serial No. not yet known, and was amended on _____ (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

(c) [X] was described and claimed in PCT International Application No. PCT/US00/18012 filed on June 29, 2000, which claims priority from U.S. Application No. 09/345,043, filed on June 30, 1999.

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information:

[X] which is material to the patentability as defined in 37, Code of Federal Regulations, § 1.56.

(also check the following, if desired)

[ ] and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent, and

[ ] In compliance with this duty there is attached an information disclosure statement in accordance with 37 CFR 1.98.

PRIORITY CLAIM (35 U.S.C. § 119)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) [] no such applications have been filed.
(e) [X] such applications have been filed as follows:

NOTE: Where item (c) is entered above and the International Application which designated the U.S. claimed priority, check item (e), enter the details below and make the priority claim.

PCT APPLICATION(S) FILED MORE THAN 12 MONTHS PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119

COUNTRY	APPLICATION NUMBER	DATE OF FILING (Day, Month, Year)	PRIORITY CLAIMED UNDER 37 USC 119

PCT	PCT/US00/18012	June 29, 2000	[X] YES [ ] NO

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete "Added Pages to Combined Declaration and Power of Attorney for Divisional, Continuation, or C-I-P Application" for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(List name and registration number.)*

Daniel S. Hodgins	Registration No. 31,026
Daniel D. Chapman	Registration No. 32,726
Cline H. White	Registration No. 45,213
William B. Nash	Registration No. 33,743
Mark H. Miller	Registration No. 29,197
Thomas Sisson	Registration No. 29,348
Richard R. Ruble	Registration No. 45,720

(check the following item, if applicable)

[ ] Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO:

Daniel S. Hodgins
JACKSON WALKER, LLP
112 E. Pecan, Suite 2100
San Antonio, Texas 78205

DIRECT TELEPHONE CALLS TO:
(Name and Telephone Number)

Daniel S. Hodgins
(210) 978-7700

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURES

FULL NAME OF SOLE/FIRST INVENTOR	Scott Cordray
INVENTOR'S SIGNATURE	Scott A. Cordray
DATE OF EXECUTION	3-17-03
COUNTRY OF CITIZENSHIP	United States
RESIDENTIAL ADDRESS	Tulsa, Oklahoma
POST OFFICE ADDRESS	1145 Utica, Ste. 513, Tulsa, Oklahoma 74104

If no further pages form a part of this Declaration then end this Declaration with this page and check the following item:

[X] This declaration ends with this page.

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited on the date shown below with the United States Postal Service in an envelope addressed to the "Commissioner of Patents and Trademarks, Washington, D.C. 20231", as follows:

37 CFR 1.8(a)	37 CFR 1.10
[ ] With sufficient postage as First Class Mail.	[ ] As "Express Mail Post Office to Addressee", Mailing Label No. _____.
Date: 3/20, 2003.	Date: _____, 20____.

Michelle Grosche
Printed Name of Person Mailing Paper or Fee

Michelle Grosche
Signature of Person Mailing Paper or Fee

PCT Help Desk
United States Patent and Trademark Office
Box PCT
Washington, DC 20231
Telephone: (703) 305-3257
Facsimile: (703) 305-2919

Facsimile Cover Sheet

To:	Daniel Hodgins	**From:**	Dan Stemmer
Fax:	210-978-7790	**Pages:**	3 (including this page)
Phone:	210-978-7700	**Date:**	10 March 03
Re:	10/018,953	**CC:**	

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

Copy of Notification of Abandonment mailed 11/15/02 and copy of Notification of Missing Requirements mailed 2/22/02.

Change of address faxed 2/20/03 has been entered.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT
United States Patent and Trademark Office
Washington, D.C. 20231

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/018,953	Scott Cordray	P-120873.1PCT US

INTERNATIONAL APPLICATION NO.	
PCT/US00/18012	
LA. FILING DATE	PRIORITY DATE
06/30/2000	06/30/1999

Daniel S Hodgins
Jackson Walker
300 Convent Street
Suite 1650
San Antonio, TX 78205

CONFIRMATION NO. 5981

371
ABANDONMENT/TERMINATION
LETTER

OC000000009112165

Date Mailed: 11/15/2002

NOTIFICATION OF ABANDONMENT

The United States Patent and Trademark Office in its capacity as an Elected Office (37 CFR 1.495), has made the following determination:

- Applicant has failed to respond to the notification of MISSING REQUIREMENTS, mailed 02/22/2002 within the time period set therein.

Therefore, the above identified application failed to meet the requirements of 35 U.S.C. 371 and 37 CFR 1.495, and is ABANDONED AS TO THE UNITED STATES OF AMERICA.

PATRICIA A BOOKER

Telephone: (703) 305-3738

PART 1 - ATTORNEY/APPLICANT COPY

FORM PCT/DO/EO/909 (371 Abandonment Notice)

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO
10/018,953	Scott Cordray	P-120873.1PCT US

INTERNATIONAL APPLICATION NO.	
PCT/US00/18012	
I.A. FILING DATE	PRIORITY DATE
06/30/2000	06/30/1999

Daniel S Hodgins
Jackson Walker
300 Convent Street
Suite 1650
San Antonio, TX 78205

CONFIRMATION NO. 5981

371 FORMALITIES LETTER

OC000000007492210

Date Mailed: 02/22/2002

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fees
- Indication of Small Entity Status
- Priority Document
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- Request for Immediate Examination
- Small Entity Statement

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the international application number and international filing date.

- $65 Surcharge for providing the oath or declaration later than the appropriate 30 months months from the priority date (37 CFR 1.492(e)) is required.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTH FROM THE DATE OF THIS NOTICE OR BY 22 or 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

2-22-02 no fee

703-308-1202

Office of Initial Examination

-305-3258

stamnes
1/018, 953
703 308 2066

Petition for receipt

Petition for Non Receipt

MPEP 711.03 C II

Pet to with.
Based on failure
to rece

703-
308-
6459

Fax Petition
to this #

Samuel Paul Stinnes
703-308-2066

atty.

703-
or Reed Smith 10/018,95

1/21/01. Filed
11/15/02 to examiner
11/23/02 Missing requirements Sent back to filedam
2/22/03 Sent

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	3505
CONNECTION TEL	17033084407#120873#00001
CONNECTION ID	TC1600 CUS SRV
ST. TIME	02/20 10:14
USAGE T	00'56
PGS. SENT	6
RESULT	OK

Chumella Gollamudi
703-305-2147
16/6
Sent

ATTORNEYS & COUNSELORS
112 E. Pecan Street Suite 2100
San Antonio, Texas 78205
(210) 978-7700, Fax (210) 978-7790
www.jw.com

JW
JACKSON WALKER L.L.P.

703 305 3620

FACSIMILE

DATE: February 20, 2003

TOTAL PAGE COUNT:

FROM: Michelle Grosche

DIRECT DIAL NUMBER: (210) 978-7768

NAME	COMPANY NAME	FACSIMILE NUMBER	PHONE NUMBER
Renee	U.S. PTO	1-703-308-4407	

PLEASE CALL (210) 978-7700
IF YOU DO NOT RECEIVE ALL PAGES.

FOR INTERNAL USE ONLY:

CLIENT/MATTER NO.: 120873.1

TIMEKEEPER: DSH2

MESSAGE:

Attached is a facsimile of a change of address that was again filed December 3

ATTORNEYS & COUNSELORS
112 E. Pecan Street Suite 2100
San Antonio, Texas 78205
(210) 978-7700, Fax (210) 978-7790
www.jw.com

JACKSON WALKER L.L.P.

FACSIMILE

DATE: February 20, 2003

TOTAL PAGE COUNT:

FROM: Michelle Grosche

DIRECT DIAL NUMBER: (210) 978-7768

NAME	COMPANY NAME	FACSIMILE NUMBER	PHONE NUMBER
Renee	U.S. PTO	1-703-308-4407	

PLEASE CALL (210) 978-7700
IF YOU DO NOT RECEIVE ALL PAGES.

FOR INTERNAL USE ONLY:

CLIENT/MATTER NO.: 120873.1

TIMEKEEPER: DSH2

MESSAGE:

Attached is a facsimile of a change of address that was again filed December 3, 2002 and the stamped postcard, stating the address change was filed on December 21, 2002. I am assuming at that time someone called about the same thing so we refiled it.

Please call if you need anything else

Austin
Dallas
Fort Worth
Houston
Richardson
San Angelo
San Antonio

Member of GLOBALAW™

RCH RE

und Trade
the items

DOCKET NO. P-120873.1(PCT)(US)
SERIAL NO.: PCT/US/18012 10/018953
FILING DATE: June 29, 2000
APPLICANT: Scott Cordray
TITLE: **NASAL SPRAY HAVING DEAD SEA SALT**

Atty. DSH

The Assistant Commissioner of Trademarks (with the Patent and Trademark Office acknowledges, and has stamped hereon the date of, receipt of the items checked bel which were mailed: December 21, 2001.

[X] EXPRESS MAIL CERTIFICATE
[X] TRANSMITTAL LETTER
[X] INTERNATIONAL PATENT APPLICATION; SEARCH REPORT
[X] RESPONSE TO FIRST WRITTEN OPINION
[X] CHANGE OF ADDRESS
[X] CHECK IN THE AMOUNT OF $698.00

U.S. Express Mail #EL406099888US

RECEIVED
JAN 11 2002

JC18 Rec'd PCT/PTO 21 DEC 2001 By

DOCKET NO. P-120873.1(PCT)(US) Atty. DSH
SERIAL. NO.: 10/018,953
FILED: December 21, 2001
APPLICANT: Scott Cordray
TITLE: NASAL SPRAY HAVING DEAD SEA SALT

The Assistant Commissioner of Patents (with the Patent and Trademark Office) acknowledges, and has stamped hereon the date of, receipt of the items checked below which were mailed: **January 21, 2003.**

[X] Status Check

U.S. First Class Mail

3298374v1

DOCKET NO. P-120873.1(PCT)(US) Atty. DSH
SERIAL. NO.: 10/018,953
FILED: December 21, 2001
APPLICANT: Scott Cordray
TITLE: NASAL SPRAY HAVING DEAD SEA SALT

The Assistant Commissioner of Patents (with the Patent and Trademark Office) acknowledges, and has stamped hereon the date of, receipt of the items checked below which were mailed: **January 21, 2003.**

[X] Status Check

U.S. First Class Mail

3298374v1

THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Scott Cordray	ATTY DKT NO. P-120873
SERIAL NO. 10/018,953	GROUP ART UNIT: Unassigned
FILED: December 21, 2001	EXAMINER: Unassigned
TITLE: NASAL SPRAY HAVING DEAD SEA SALT	

TO: Box Patent Application
ATTN: STATUS/NO FEE
Commissioner of Patents and Trademarks
Washington, D.C. 20231

STATUS INQUIRY

1. More than 2 years have passed since:

   [X] NEW APPLICATIONS

   The filing of this application on December 21, 2001 and No communication has been received from the Patent and Trademark Office indicating action on this application.

2. Kindly advise the undersigned of the present status of this application, by checking the appropriate box on the next page. A stamped return-addressed envelope is provided.

Respectfully submitted,

JACKSON WALKER LLP
112 E. Pecan, Suite 2100
San Antonio, TX 78205
(210) 978-7700
(210) 978-7790

By _____
Daniel S. Hodgins
Regis. No. 31,026

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2789
CONNECTION TEL	17033053230#120873#00001
CONNECTION ID	USPTO/PCT OPEP
ST. TIME	12/03 13:10
USAGE T	00'34
PGS. SENT	4
RESULT	OK

ATTORNEYS & COUNSELORS
112 E. Pecan Street Suite 2100
San Antonio, Texas 78205
(210) 978-7700, Fax (210) 978-7790
www.jw.com

JACKSON WALKER L.L.P.

FACSIMILE

DATE: December 3, 2002

TOTAL PAGE COUNT: 4

FROM: Daniel S. Hodgins

DIRECT DIAL NUMBER: (210) 228-2408

NAME	COMPANY NAME	FACSIMILE NUMBER	PHONE NUMBER
Mrs. Kathy Short		(703) 305-3230	

PLEASE CALL (210) 228-2408
IF YOU DO NOT RECEIVE ALL PAGES.

FOR INTERNAL USE ONLY:

CLIENT/MATTER NO.: 120873.01

TIMEKEEPER: DSH2

MESSAGE:

Please see attached documents.

ATTORNEYS & COUNSELORS
112 East Pecan Street, Suite 2100
San Antonio, Texas 78205
(210) 978-7700 • fax (210) 978-7790
www.jw.com

JACKSON WALKER L.L.P.

Daniel S. Hodgins
(210) 228-2408
dhodgins@jw.com

December 3, 2002

Mrs. Kathy Short
Commissioner for Patents
Washington, D.C. 20231-9999

Re: U.S. Patent Application Serial No. 10/018,953 for NASAL SPRAY HAVING DEAD SEA SALT
Our File No. P-120873.01(PCT)(US)

Dear Mrs. Short:

Enclosed please find a Change of Attorney Contact/Address In Patent Application for the above captioned patent application. Pursuant to my secretary's telephone conference with your office, your records reflect a wrong address for my firm. Please send all necessary documents to 112 E. Pecan, Ste. 2100, San Antonio, Texas 78205. We received a receipt postcard at the correct address, but never received any other documents due to the wrong address. If you have any questions, please feel free to give me a call.

Sincerely,

DANIEL S. HODGINS

DSH:eja

Enclosures

3271063v1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Scott Cordray SERIAL NO. 10/018,953 FILING DATE: 12/21/2001 TITLE: **NASAL SPRAY HAVING DEAD SEA SALT**	ATTY DKT NO. **P-120873.1(PCT)(US)**
TO: Box PCT Commissioner of Patents and Trademarks Washington, DC 20231	

CHANGE OF ATTORNEY CONTACT/ADDRESS IN PATENT APPLICATION

The undersigned attorney has merged with Jackson Walker, L.L.P. Please update your records to send all correspondence, or direct all telephone calls to:

Daniel S. Hodgins
Jackson Walker, L.L.P.
112 E. Pecan, Suite 2100
San Antonio, Texas 78205
(210) 978-7700
(210) 978-7790

Respectfully submitted,

JACKSON WALKER, LLP
112 E. Pecan, Suite 2100
San Antonio, TX 78205
(210) 978-7700
(210) 978-7790 (Fax)

By _____
Daniel S. Hodgins
Regis. No. 31,026

PTO/SB/97 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Certificate of Transmission under 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office

on December 3, 2002.
Date


Signature

Daniel S. Hodgins
Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of transmission, or this certificate must identify each submitted paper.

Change of Attorney Contact/Address In Patent Application

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY
UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Scott Cordray	) Atty. Dkt. No.: COR170-10/99121 PCT
International Serial No.:	PCT/US00/18012	)
International Filing Date:	30 June 2000	)

Title: NASAL SPRAY HAVING DEAD SEA SALT

Box PCT
Director for Patents & Trademarks
Washington, D.C. 20231

TRANSMITTAL LETTER

Enclosed herewith in connection with the above-referenced international patent application are the following:

[X] Statement under article 34(b).

[X] Withdrawal of Head, Johnson & Kachigian as attorneys of record and Change of Address for Daniel S. Hodgins, Attorney of Record.

[X] pre-addressed postcard

Respectfully submitted,

Daniel S. Hodgins, Reg. No. 31,026
JACKSON WALKER, LLP
112 E. Pecan St., Ste. 2100
San Antonio, TX 78205
Tel: (210)978-7700
Fax: (210)978-7790

Attorney for Applicant

Espress Mail No.: EL555989870US
Date Mailed: July 5, 2001

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY
UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Scott Cordray	) Atty. Dkt. No.: COR170-10/99121 PCT
International Serial No.:	PCT/US00/18012	)
International Filing Date:	30 June 2000	)

Title: NASAL SPRAY HAVING DEAD SEA SALT

Box PCT
Director for Patents & Trademarks
Washington, D.C. 20231

WITHDRAWAL OF ATTORNEYS OF RECORD ASSOCIATED WITH HEAD, JOHNSON, & KACHIGIAN AND CHANGE OF ADDRESS FOR DANIEL S. HODGINS

I hereby apply to withdraw Head, Johnson & Kachigian as attorneys of record in the above-identified international patent application.

Effective herewith, Daniel S. Hodgins will be employed by the firm of Jackson Walker LLP, and the Applicant herein requests that he continue as attorney of record in this application.

Please change the address of the attorney of record and direct all future correspondence to:

Daniel S. Hodgins, Reg. No. 31,026
JACKSON WALKER, LLP
112 E. Pecan St., Ste. 2100
San Antonio, TX 78205
Tel: (210)978-7700
Fax: (210)978-7790

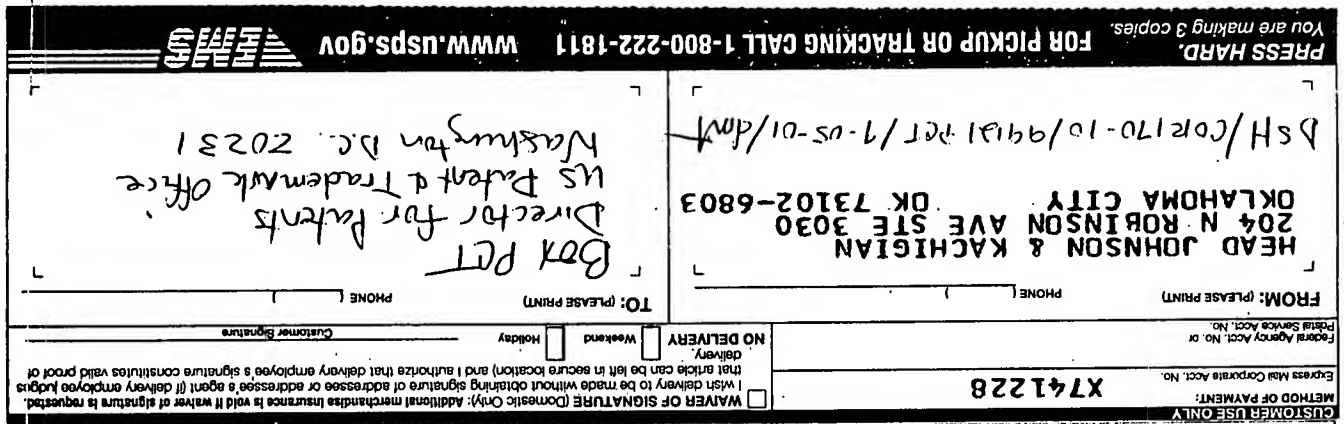
It is certified that the person whose signature appears below has the authority to change the correspondence address for the above-referenced international application.

Respectfully submitted,

Daniel S. Hodgins, Reg. No. 31,026
JACKSON WALKER, LLP
112 E. Pecan St., Ste. 2100
San Antonio, TX 78205
Tel: (210)978-7700 Fax: (210)978-7790

Attorney for Applicant

Express Mail No.: EL555989870US
Date Mailed: July 5, 2001



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FOR PICKUP OR TRACKING CALL 1-800-222-1811 www.usps.gov
EMS
FROM: (PLEASE PRINT) PHONE ( )
HEAD JOHNSON & KACHIGIAN
204 N ROBINSON AVE STE 3030
OKLAHOMA CITY OK 73102-6803
DSH/COR170-10/99121 PCT/7-05-01/dmt
TO: (PLEASE PRINT) PHONE ( )
Box PCT
Director for Patents
US Patent & Trademark Office
Washington D.C. 20231
Express Mail Corporate Acct. No. X741228
Federal Agency Acct. No. or Postal Service Acct. No.
WAIVER OF SIGNATURE (Domestic Only): Additional merchandise insurance is void if waiver of signature is requested. I wish delivery to be made without obtaining signature of addressee or addressee's agent (if delivery employee judges that article can be left in secure location) and I authorize that delivery employee's signature constitutes valid proof of delivery.
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NO DELIVERY Weekend Holiday Customer Signature

FROM: (PLEASE PRINT) PHONE ( )
HEAD JOHNSON & KACHIGIAN
204 N ROBINSON AVE STE 3030
OKLAHOMA CITY OK 73102-6803
DSH/COR170-10/99121 PCT/7-05-01/dmt

TO: (PLEASE PRINT) PHONE ( )
Box PCT
Director for Patents
US Patent & Trademark Office
Washington D.C. 20231

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EMS

PATENT COOPERATION TREATY

FEB 11 2002

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
DANIEL S. HODGINS
HEAD, JOHNSON & KACHIGIAN
228 WEST 17TH PLACE
TULSA, OK 74119

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing (*day/month/year*)	31 JAN 2002
Applicant's or agent's file reference 99121	**IMPORTANT NOTIFICATION**

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US00/18012	30 June 2000 (30.06.2000)	30 June 1999 (30.06.1999)

Applicant

CORDRAY, SCOTT

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer John Pak Telephone No. (703) 308-1235

Form PCT/IPEA/416 (July 1992)

THE BACK OF THIS DOCUMENT CONTAINS A SIMULATED WATERMARK

339994

JACKSON WALKER L.L.P.

ATTORNEYS AND COUNSELORS

901 Main Street, Suite 6000, Dallas, Texas 75202
(214) 953-6000 Fax (214) 953-5822

Austin Dallas Ft. Worth Houston Richardson San Angelo San Antonio

Bank of America
Dallas, Tx

339994

Check Date: 12/20/2001

$ ***698.00***

DOLLARS

Six hundred ninety-eight and 00/100**********

Req. # 241922

PAY TO THE ORDER OF

Commissioner of Patents
PO Box 16
Washington, DC 20231

James S. Ga

AUTHORIZED SIGNATURE

⑈339994⑈ ⑆111000025⑆ ⑈0180472852⑈ ⑈0000069800⑈

PATENT AND TRADEMARK OFFICE
-13-10-0001
01-03-2002
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JAN -1 02

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056007387 ES945 10 P10
01/04/02

VS DATE 01/04/02
P21 E C 087 NT

DOCKET NO. P-120873.1(PCT)(US) Atty. D
SERIAL NO.: PCT/US/18012
FILING DATE: June 29, 2000
APPLICANT: Scott Cordray
TITLE: **NASAL SPRAY HAVING DEAD SEA SALT**

The Assistant Commissioner of Trademarks (with the Patent and Trademark O acknowledges, and has stamped hereon the date of, receipt of the items checke which were mailed: December 21, 2001.

[X] EXPRESS MAIL CERTIFICATE
[X] TRANSMITTAL LETTER
[X] INTERNATIONAL PATENT APPLICATION; SEARCH REPORT
[X] RESPONSE TO FIRST WRITTEN OPINION
[X] CHANGE OF ADDRESS
[X] CHECK IN THE AMOUNT OF $698.00

U.S. Express Mail #EL406099888US

Atty. DSH

DOCKET NO. P-120873.1(PCT)(US)
SERIAL NO.: PCT/US/18012
FILING DATE: June 29, 2000
APPLICANT: Scott Cordray
TITLE: **NASAL SPRAY HAVING DEAD SEA SALT**

10/018953

The Assistant Commissioner of Trademarks (with the Patent and Trademark Office acknowledges, and has stamped hereon the date of, receipt of the items checked be which were mailed: December 21, 2001.

[X] EXPRESS MAIL CERTIFICATE
[X] TRANSMITTAL LETTER
[X] INTERNATIONAL PATENT APPLICATION; SEARCH REPORT
[X] RESPONSE TO FIRST WRITTEN OPINION
[X] CHANGE OF ADDRESS
[X] CHECK IN THE AMOUNT OF $698.00

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Customer Signature

75/ 200

F02
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FROM: (PLEASE PRINT) PHONE (210) 978-7700

JACKSON WALKER LLP
112 E PECAN ST STE 2100
SAN ANTONIO TX 78205-1517

120873.1 | DSH2

TO: (PLEASE PRINT) PHONE ( )

ATTENTION: BOX PCT
COMMISSIONER OF PATENTS
AND TRADEMARKS
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Scott Cordray International Application No.: PCT/US/18012 International Filing Date: June 29, 2000 TITLE: **NASAL SPRAY HAVING DEAD SEA SALT**	ATTY DKT NO. P-120873.1(PCT)(US)
TO: Box PCT Commissioner of Patents and Trademarks Washington, DC 20231	

EXPRESS MAIL CERTIFICATE

Express mail label number EL406099888US

Date of deposit 12-21-01

I hereby certify that the following attached papers and fees

1. Transmittal letter;
2. International patent application;
3. International Search Report;
4. Response to First Written Opinion;
5. Check for $698.00;
6. Acknowledged postcard.

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and addressed to Box PCT, Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Elva J. Abundis

3058916v1

EL406099888US

FORM PTO-1390 (REV 11-98) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
P-120873.1PCT US	
U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US00/18012	30 June 2000	20 June 1999

TITLE OF INVENTION
NASAL SPRAY HAVING DEAD SEA SALT

APPLICANT(S) FOR DO/EO/US
SCOTT CORDRAY

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [X] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [X] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [X] A change of power of attorney and/or address letter.
16. [ ] Other items or information:

(January 1999)

U.S. APPLICATION NO. (If Known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
	PCT/US00/18012	B-120873.1PCT US

17. [X] The following fees are submitted:	CALCULATIONS PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):	
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO $970.00	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO $840.00	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO $760.00	
International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) $670.00	
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) $96.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 970.00
Surcharge of $130.00 for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	- 20 =	15	X $18.00	$ 270.00
Independent claims	- 3 =		X $78.00	$ 156.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $260.00	$
TOTAL OF ABOVE CALCULATIONS =				$
Reduction of 1/2 for filing by small entity, if applicable. A Small Entity Statement must also by filed (Note 37 CFR 1.9, 1.27, 1.28).				$ 698.00
SUBTOTAL =				$ 698.00
Processing fee of $130.00 for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$
TOTAL NATIONAL FEE =				$
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property +				$
TOTAL FEES ENCLOSED =				$ 698.00
			Amount to be: refunded	$
			charged	$

a. [X] A check in the amount of $ 698.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-2400. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Daniel S. Hodgins

SIGNATURE:

Daniel S. Hodgins

NAME

31,026

REGISTRATION NUMBER

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
DANIEL S. HODGINS
HEAD, JOHNSON & KACHIGIAN
228 WEST 17TH PLACE
TULSA, OK 74119

RECEIVED
AUG 31 2000
HEAD, JOHNSON & KACHIGIAN

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 99121	Date of Mailing *(day/month/year)* 28 AUG 2000
	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US00/18012	International filing date *(day/month/year)* 30 June 2000 (30.06.2000)
Applicant CORDRAY, SCOTT	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.
Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompany sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application , or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Frank Choi Telephone No. (703) 308-1235

Form PCT/ISA/220 (July 1998)

DOCKET RECEIVED
ATTORNEY DSH
AUG 31 2000
ACTION DUE: Response to Search Rpt Due 10-28-00
SET UP:

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
DANIEL S. HODGINS
HEAD, JOHNSON & KACHIGIAN
228 WEST 17TH PLACE
TULSA, OK 74119

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 99121	Date of Mailing *(day/month/year)* 28 AUG 2000
	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US00/18012	International filing date *(day/month/year)* 30 June 2000 (30.06.2000)
Applicant CORDRAY, SCOTT	

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When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompany sheet.

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34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

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4. **Further action(s):** The applicant is reminded of the following:

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Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Frank Choi Telephone No. (703) 308-1235

Form PCT/ISA/220 (July 1998)

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 99121	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US00/18012	International filing date (*day/month/year*) 30 June 2000 (30.06.2000)	(Earliest) Priority Date (*day/month/year*) 30 June 1999 (30.06.1999)
Applicant CORDRAY, SCOTT		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
   ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:
   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
2. ☐ **Certain claims were found unsearchable** (See Box I).
3. ☐ **Unity of invention is lacking** (See Box II).
4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the **drawings** to be published with the abstract is Figure No.
   ☐ as suggested by the applicant.
   ☐ because the applicant failed to suggest a figure.
   ☐ because this figure better characterizes the invention.
   ☐ None of the figures

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/18012

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 33/00, 33/06, 33/14
US CL : 424/663,665,677,678,679,680,681,682,722,723;514/853

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 424/663,665,677,678,679,680,681,682,722,723;514/853

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Remington's Pharmaceutical Sciences (17th Ed. 1985)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	EP 0 937 453 A2 (SCHWARTZ) 25 August 1999 (25.08.1999), pg. 3, lines 26-39, pg. 8, lines 23,24.	1,5-10, 14-20, 24-26
Y,P		2-4, 11-13, 21-23, 27-35
Y	GENNARO, A. R. Remington's Pharmaceutical Sciences (17th Edition) Easton, Pennsylvania: Mack Publishing Company. 1985, pages 1293, 1500, 1662-1677.	2-4, 11-13, 21-23, 27-35

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 August 2000 (11.08.2000)	28 AUG 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Frank Choi Telephone No. (703) 308-1235

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/18012

Continuation of B. FIELDS SEARCHED Item 3: STN/CAS,WEST
search terms: Dead Sea salts,nasal,magnesium,potassium,sodium,calcium,chloride,bromide

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(71) Applicant and
(72) Inventor: CORDRAY, Scott [US/US]; 4125 South Chestnut Avenue, Broken Arrow, OK 74011 (US).

(74) Agent: HODGINS, Daniel, S.; Head, Johnson & Kachigian, 228 West 17th Place, Tulsa, OK 74119 (US).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: NASAL SPRAY HAVING DEAD SEA SALTS

(57) Abstract: A nasal spray formulation for use with the treatment of rhinitis, sinusitis, epistaxis and post-surgical irrigation. The nasal spray formulation includes the Dead Sea salt or its equivalent. The composition of the Dead Sea salt mixture includes about 31-35 % magnesium halide, about 24-26 % potassium halide, about 4-8 % sodium halide, about 0.4-0.6 % calcium halide, the halide being about 0.3-0.6 % bromide, about 99.4-99.7 % chloride, and may also include about 0.05-0.2 % sulphates, about 0.5-0.2 % insolubles. The salts may comprise about 34-38 % water of crystallization. The spray formulation is about 0.5 to about 5 grams per liter of sterile aqueous solution, contains a buffer, and is essentially free of noxious, organic impurities.

WO 01/00218 A1

NASAL SPRAY HAVING DEAD SEA SALTS

BACKGROUND OF THE INVENTION

This is a continuation-in-part application of co-pending serial number 09/345,043, filed June 30, 1999. The present invention relates to a nasal spray formulation used in the treatment of conditions involving the nasal cavity and related passageways. Specifically, the formulation utilizes Dead Sea salts or analogous combinations to assist in the treatment of rhinitis, sinusitis, epistaxis, post-surgical irrigation and the like.

The Dead Sea is one of the most saline lakes in the world. It lies between the hills of Judaea to the west and the Transjordanian plateaus to the east. The Jordan River flows from the north into the Dead Sea. About 2.5 million years ago, heavy stream flow into the lake deposited thick sediments containing shale, clay, sandstone, rock salt, and gypsum. After this, strata of clay, marl, soft chalk, and gypsum fell upon layers of sand and gravel. Having no outlet, the Dead Sea is a "terminal lake" which loses huge amounts of water by evaporation in the hot dry air. The water has evaporated faster than it has been replenished by precipitation over the last 10,000 years, which has resulted in the lake gradually shrinking to its present form. Because of this, bare deposits cover the Dead Sea valley to a thickness of 1 to 4 miles (1.6 to 6.4 km). This water evaporation has also resulted in high concentrations of salts and minerals in a unique composition that is particularly rich in magnesium, sodium, potassium, calcium, bromide and various other minor anions such as, e.g., sulfate. The concentration of salt increases toward the Dead Sea bottom. Down to 130 feet (40m), the temperature varies from 66 ° to 98 ° F (19° to 37° C), and the salinity is slightly less than 300 parts per thousand. At this depth, the water is particularly rich in sulfates and in bicarbonates. There is a transition zone located between 130 and 330 feet (40 and 100 m). The lower waters below 330 ft (100m) have a uniform temperature of about

72°F (22°C) and a higher degree of salinity (approximately 332 parts per thousand). This lower water contains hydrogen sulfide and strong concentrations of magnesium, potassium, chlorine, and bromine. Below this, the deepest waters are saturated with sodium chloride, which is precipitated to the bottom. The lower waters are fossilized--they remain permanently on the bottom because they are very salty and dense. The upper waters date from a few centuries A.D.

Certain references describe the use of the Dead Sea salts, but not in connection with the treatment of nasal conditions. See U.S. Pat. 4,943,432 issued to Biener on July 24, 1990 which mentions the use of Dead Sea salts for use with psoriasis, atopic dermatitis and other skin diseases. See also, U.S. Pat. 5,707,631 issued to Lieberman on January 13, 1998 which describes the use of Dead Sea salts in connection with a herbal composition for use with the treatment of arthritis, blood pressure and Alzheimer's disease.

Further, earlier references list nasal sprays but none which utilizes the Dead Sea salts in the treatment of rhinitis, sinusitis, epistaxis and post-surgical irrigation. See U.S. Pat. 5,840,278 issued to Coleman on November 24, 1998 which indicates use of a nasal spray having a mineral component, a vitamin component and aloe vera for a cold virus remedy. Due to unknown and unexpected complications caused by aloe vera in the treatment of rhinitis, sinusitis, epistaxis and post-surgical irrigation, this formulation may not be best suited for such treatment.

Accordingly, an important object of the invention is to create a formulation in the treatment of conditions of the nasal cavity and passageway.

Another object of the invention is to create a formulation for the treatment of rhinitis, sinusitis, epistaxis and post-surgical irrigation.

Another object of the invention is to create a formulation utilizing the Dead Sea salts for the treatment of rhinitis, sinusitis, epistaxis and post-surgical irrigation.

SUMMARY OF THE INVENTION

In accordance with the above and related objects, the present invention provides a nasal spray formulation for use with the treatment of rhinitis, sinusitis, epistaxis, post-surgical irrigation and the like. The nasal spray formulation includes about 1-5% Dead Sea salt or its equivalent. The composition of the Dead Sea salt mixture includes about 31-35% magnesium halide, about 24-26% potassium halide, about 4-8% sodium halide, about 0.4-0.6% calcium halide, the halide being about 0.3 -0.6% bromide, about 99.4-99.7% chloride. The salt may also include about 0.05-0.2% sulphates, and about 0.5-0.2% insolubles, the latter of which is preferably removed by appropriate filtrations or other means. The salts may comprise about 34-38% water of crystallization. The spray formulation is about 0.5 to about 5.0 grams per liter of aqueous solution. Preferably, the aqueous solution is sterile and contains a buffer, which maintains the pH between 6.5 and 7.5. The spray formulation is preferably also essentially free of noxious organic impurities. "About" in this application means $\pm$ 20%.

Methods for treatment are included in the present invention. In one particular embodiment, the claimed method involves treating symptoms of adverse conditions effecting the nasal cavity and related passageways, which involves identifying a patient with an adverse nasal cavity condition and obtaining a premixed formulation containing a Dead Sea salt or the equivalent formulation and mineral composition in aqueous solution and administering or self-administering an aerosol formed from the formulation at least 1 time a day as symptoms of the patient or individual persist.

A method of producing is also part of the present invention and the formulations which includes dissolving the Dead sea salt in aqueous solution and storing this premixed formulation in a container suitable for nasal aerosol administration.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention relates to a nasal spray formulation used in the treatment of conditions involving the nasal passageway. Specifically, the formulation utilizes the Dead Sea salts to assist in the treatment of rhinitis, sinusitis, epistaxis, and post-surgical irrigation. Rhinitis is the inflamation of the mucous membranes of the nose. Sinusitis is the inflamation of the sinus. Epistaxis is nose bleed or hemorrahage from the nose.

In a preferred embodiment of the present invention, the Dead Sea salt solution comprises about 0.5 to about 5.0 grams per liter of sterile aqueous solution. Said aqueous solution may be or include a buffer, water, or any other pharmacologically acceptable aqueous mixture. The buffer is to maintain the pH between about 6.5 and 7.5. A buffer is Sodium Phosphate, Potassium Phosphate, Sodium Carbonate, or such other as would be used by those skilled in the art to maintain the pH between 6.5 and 7.5. The composition of the Dead Sea salt mixture includes about 31-35% magnesium halide, about 24-26% potassium halide, about 4-8% sodium halide, about 0.4-0.6% calcium halide. The halide are preferably about 0.3 -0.6% bromide, 99.4-99.7% chloride, and the mixture may also include about 0.05-0.2% sulphates, about 0.5-0.2% insolubles, the later of which are preferably removed by filtrates. The salts may comprise about 34-38% water of crystallization. The formulation is essentially free of noxious organic impurities, such as human waste, dead marine animals, and fossil fuel spillage. "Essentially Free" is defined as no more than harmless, trace quantities.

Although the preferred embodiment of this invention is the use of Dead Sea salt from the Dead Sea, it is understood that one skilled in the art would be able to artificially create a Dead Sea salt. It is also apparent to anyone skilled in the art, that certain pharmacologically accepted ingredients normally found in nasal spray could be added to the

instant nasal spray formulation. However, both of these circumstances are claimed within this application. The claimed invention includes both the use of actual Dead Sea salt and artificially created salt with the same or similar salt and mineral components as Dead Sea salt. Also, the addition of other pharmacologically acceptable nasal spray ingredients does not change the invention claimed in this application.

EXAMPLE

A pilot study has been performed on the Dead Sea salt nasal irrigation. Patients were given verbal and written instructions to use the Dead Sea salt nasal spray formulation for seven days, the first two days were used as a baseline with no treatment, and the patients were to evaluate their nasal stuffiness, watery, itchy eyes, runny nose, sneezing, itchy troat and cough as well as postnasal drainage. On the last five days, they also were instructed to evaluate the Dead Sea salt nasal spray's global efficacy and personal satisfaction. They utilized this medicine through a four ounce nasal squeeze bottle three to four times per day. Instructions were given to mix one teaspoon of Dead Sea salt with two cups of water and then subsequently boil this mixture for five minutes. The mixture used as a nasal spray with two sprays up each nostril three to four times per day was a 2.5% solution with 12 g of the salt crystal in two cups, or 480cc, of water.

Nasal stuffiness was improved by 42%. Watery, itchy eyes were improved by 55.5%. Runny nose was improved by 44%. Global efficacy and personal satisfaction were rated 62.5%. A few patients reported an increase of postnasal drainage by 60-70%. This is thought to be secondary to mobilization of the mucus in sinus cavities. All patients requested that they stay on Dead Sea salt formulation. One patient in particular previously had two endoscopic sinus surgeries and had been placed on IV antibiotics two times. One patient who rated the overall global efficacy as 40% and personal satisfaction as 40% stated

that after desisting use of the Dead Sea salt for five days that it was obvious that it had a greater impact as a treatment than she originally thought. This patient stated that after five days without use of the Dead Sea salt formulation that her hoarseness was back, her ears and throat were bothering her again, her mucous secretions were thicker, and she had sinus pain on the left, all of which had diminished greatly while on the Dead Sea salt irrigation.

One patient tested who had not tried other medical treatment reported the following results: nasal stuffiness-100% improved; eyes-50% improved; runny nose -100% improved; sneezing-82% improved; throat-100% improved; post nasal drainage-100% improved; global efficacy-90% improved; and personal satisfaction-100% improved.

While the invention has been described with a certain degree of particularity, it is manifest that many changes may be made in the arrangement of components without departing from the spirit and scope of this disclosure. It is understood that the invention is not limited to the embodiments set forth herein for purposes of exemplification, but is to be limited only by the scope of the attached claim or claims, including the full range of equivalency to which each element thereof is entitled.

It is understood that the sprit and scope of the present invention is embodied in the following claims.

WHAT IS CLAIMED IS:

1. A nasal spray formulation comprising:

a Dead Sea salt and mineral composition in aqueous solution.

2. The formulation of claim 1 where the aqueous solution is sterile.

3. The formulation of claim 1 defined further as containing a buffer.

4. The formulation of claim 3 where the buffer is to maintain a pH of from about 6.5 to about 7.5.

5. The formulation of claim 1 where the composition is from about 0.5 to about 5 grams per liter of aqueous solution.

6. The formulation of claim 1 where the composition is about 2.5 grams per liter of aqueous solution.

7. The formulation of claim 1 where the composition is essentially free of noxious organic impurities.

8. The formulation of claim 1 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% magnesium halide, about 24-26% potassium halide, about 4-8% sodium halide, about 0.4-0.6% calcium halide, the halide being about 0.3 -0.6% bromide and about 99.4-99.7% chloride.

9. A method of treating symptoms of adverse conditions affecting the nasal cavity and passageway, the method comprising the steps of identifying patient with an adverse nasal cavity conditions;

a. obtaining a premixed formulation containing a Dead Sea salt and mineral composition in aqueous solution; and

b. administering an aerosol formed from the formulation at least 1 time a day as symptoms of the patient persist.

10. The method of claim 9 wherein said conditions include rhinitis, sinusitis, epistaxis and post-surgical irritation.

11. The method of claim 9 wherein said Dead Sea salt and mineral composition is in sterile aqueous solution.

12. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution contains a buffer.

13. The method of claim 12 wherein the buffer is to maintain a pH from about 6.5 to about 7.5.

14. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution is from about 0.5 to about 5 grams of salt per liter of said aqueous solution.

15. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution is about 2.5 grams of salt per liter of said aqueous solution.

16. The method of claim 9 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% magnesium halide, about 24-26% potassium halide, about 4-8% sodium halide, about 0.4-0.6% calcium halide, the halide being about 0.3-0.6% bromide and about 99.4-99.7% chloride.

17. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution is essentially free of organic impurities.

18. A method for treating symptoms of adverse conditions of the nasal cavity and passageway with a Dead Sea salt and mineral composition in aqueous solution, the method comprising the steps of obtaining a premixed formulation containing a Dead Sea salt mineral composition in aqueous solution; and self administering an aerosol formed from said formulations nasally at least 1 time a day as symptoms persist.

19. The method for claim 18 wherein said conditions include rhinitis, sinusitis, epistaxis and post-surgical irritation.

20. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution is from about 0.5 to about 5 grams per liter of said aqueous solution.

21. The method of claim 18 wherein a Dead Sea salt mineral composition is in sterile aqueous solution.

22. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution contains a buffer.

23. The method of claim 22 wherein the buffer is to maintain a pH of from about 6.5 to about 7.5.

24. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution is about 2.5 grams per liter of said aqueous solution.

25. The method of claim 18 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% magnesium halide, about 24-26% potassium halide, about 4-8% sodium halide, about 0.4-0.6% calcium halide, the halide being about 0.3 -0.6% bromide and about 99.4-99.7% chloride.

26. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution is essentially free of noxious, organic impurities.

27. A method of producing a nasal spray formulation comprising Dead Sea salt in aqueous solution, the method comprising dissolving Dead Sea salt in aqueous solution and storing this premixed formulation in a container suitable for aerosol nasal administration.

28. The method of claim 27 wherein a Dead Sea salt mineral composition in aqueous

solution is from about 0.5 to about 5 grams per liter of said aqueous solution.

29. The method of claim 27 wherein Dead Sea salt mineral composition in aqueous solution is about 2.5 grams per liter of said aqueous solution.

30. The method of claim 27 wherein Dead Sea salt mineral composition is in sterile aqueous solution.

31. The method of claim 27 wherein Dead Sea salt mineral composition in sterile aqueous solution contains a buffer.

32. The method of claim 31 wherein the buffer is to maintain a pH of from about 6.5 to about 7.5.

33. The method of claim 27 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% magnesium halide, about 24-26% potassium halide, about 4-8% sodium halide, about 0.4-0.6% calcium halide, and halide being about 0.3 -0.6% bromide and about 99.4-99.7% chloride.

34. The method of claim 27 wherein a Dead Sea salt mineral composition in aqueous solution is essentially free of noxious, organic impurities.

35. A nasal spray formulation comprising a Dead Sea salt and mineral composition having about 31-35% magnesium halide, about 24-26% potassium halide, about 4-8%

sodium halide, about 0.4-0.6% calcium halide, the halide being about 0.3 -0.6% bromide and about 99.4-99.7% chloride, where said Dead Sea salt and mineral composition contains a buffer maintaining a pH from about 6.5 to 7.5 and is from about 0.5 to about 5 grams per liter of sterile aqueous solution and is essentially free of noxious, organic impurities.

PCT/US00/18012

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 33/00, 33/06, 33/14

US CL : 424/663,665,677,678,679,680,681,682,722,723;514/853

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Remington's Pharmaceutical Sciences (17th Ed. 1985)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P — Y,P	EP 0 937 453 A2 (SCHWARTZ) 25 August 1999 (25.08.1999), pg. 3, lines 26-39, pg. 8, lines 23,24.	1,5-10, 14-20, 24-26 — 2-4, 11-13, 21-23, 27-35
Y	GENNARO, A. R. Remington's Pharmaceutical Sciences (17th Edition) Easton, Pennsylvania: Mack Publishing Company. 1985, pages 1293, 1500, 1662-1677.	2-4, 11-13, 21-23, 27-35

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 August 2000 (11.08.2000)	28 AUG 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Frank Choi Telephone No. (703) 308-1235

Form PCT/ISA/210 (second sheet) (July 1998)

Continuation of B. FIELDS SEARCHED Item 3: STN/CAS,WEST
search terms: Dead Sea salts,nasal,magnesium,potassium,sodium,calcium,chloride,bromide

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY
UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Scott Cordray	) Atty. Dkt. No.: COR170-10/99121 PCT
International Serial No.:	PCT/US00/18012	)
International Filing Date:	30 June 2000	)
Title:	NASAL SPRAY HAVING DEAD SEA SALT	)

Box PCT
Director for Patents & Trademarks
Washington, D.C. 20231

STATEMENT UNDER ARTICLE 34(b)

This is in response to the First Written Opinion of the International Preliminary Examination Authority mailed June 15, 2001.

Claims 1 and 2 were thought to lack novelty over Japanese Abstract 60164467, indeed this abstract concerns processed Dead Sea salts as nutritious post exercise beverage. Claims 1 and 2 of the present invention concern "a nasal spray formulation" not a beverage. Should anyone make a Dead Sea salt beverage it would appear not to be infringing claims 1 and 2 unless perhaps there was s cific advice on the beverage container to spray the beverage in one's nose.

Claims 7 d 8 were thought to lack novelty over EP 0937453 A2. Again, this reference envisions Dead Sea salt aqueous solution for an entirely different purpose. In this case the primary purpose is the cleansing of skin and of teeth. Applicant does not deny that Dead Sea salts, which have been available for thousands of years, have been previously dissolved in water and used for various purposes. However, none before the present inventor had ever discovered that a Dead Sea salt formulation is an effective nasal spray. Although EP 0937453 A2 mentions on page 8 that "a different composition of the formula can be used for inhaling to ease nasal or

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Date Mailed: July 5, 2001

sinus congestion and to soothe coughing irritations due to bronchitis or similar conditions", no guidance is given as to the nature of this "different composition of the formula." It is also noted that this is just one of many different possible uses speculated upon by this reference. The primary uses taught are cosmetic and tissue cleansing. Of course, this reference has no clinical showing of any effectiveness for nasal congestion. The present application has such clinical evidence and indeed has a specific recommended composition for such internasal usage. Thus, it is believed that EP 0937453 A2 neither teaches or renders obvious the present invention. One of skill in the art studying this European patent application would not conclude that this minor proposed usage is in fact of significance because there is no showing of evidence therefor. It is among one of many proposed uses, and a minor one at that.

Although EP 0937453A2 states that sinus or nasal problem may be eased by inhaling a different composition of the described formula, no different formulation is described and no experimental proofs are offered. Applicant proposes that this is the merest wild speculation.

Applicant requests deletion of original pages 4-5 and 8-13 and their replacement by the appended substitute pages 4-5 and 8-13. The replacement specification pages and claim pages are to correct the typographical error in the placement of a decimal point. The Example mentions a specific formulation of 12 g of Dead Sea salts per 480 ml (which is 25g/liter). The wt/wt percentage is inherent in the exemplary material.

Applicant respectfully requests a positive preliminary examination report.

Respectfully submitted,

Daniel S. Hodgins, Reg. No. 31,026
JACKSON WALKER LLP
112 E. Pecan St., Ste 2100
San Antonio, TX 78205
(210)978-7700 tel (210)978-7790 fax

Attorney for Applicant

SUBSTITUTE 4

SUMMARY OF THE INVENTION

In accordance with the above and related objects, the present invention provides a nasal spray formulation for use with the treatment of rhinitis, sinusitis, epistaxis, post-surgical irrigation and the like. The nasal spray formulation includes about 1-5% Dead Sea salt or its equivalent. The composition of the Dead Sea salt mixture includes about 31-35% magnesium halide, about 24-26% potassium halide, about 4-8% sodium halide, about 0.4-0.6% calcium halide, the halide being about 0.3 -0.6% bromide, about 99.4-99.7% chloride. The salt may also include about 0.05-0.2% sulphates, and about 0.5-0.2% insolubles, the latter of which is preferably removed by appropriate filtrations or other means. The salts may comprise about 34-38% water of crystallization. The spray formulation is about 5.0 to about 50.0 grams per liter of aqueous solution. Preferably, the aqueous solution is sterile and contains a buffer, which maintains the pH between 6.5 and 7.5. The spray formulation is preferably also essentially free of noxious organic impurities. "About" in this application means $\pm$ 20%.

Methods for treatment are included in the present invention. In one particular embodiment, the claimed method involves treating symptoms of adverse conditions effecting the nasal cavity and related passageways, which involves identifying a patient with an adverse nasal cavity condition and obtaining a premixed formulation containing a Dead Sea salt or the equivalent formulation and mineral composition in aqueous solution and administering or self-administering an aerosol formed from the formulation at least 1 time a day as symptoms of the patient or individual persist.

A method of producing is also part of the present invention and the formulations which includes dissolving the Dead sea salt in aqueous solution and storing this premixed formulation in a container suitable for nasal aerosol administration.

SUBSTITUTE 5

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention relates to a nasal spray formulation used in the treatment of conditions involving the nasal passageway. Specifically, the formulation utilizes the Dead Sea salts to assist in the treatment of rhinitis, sinusitis, epistaxis, and post-surgical irrigation. Rhinitis is the inflamation of the mucous membranes of the nose. Sinusitis is the inflamation of the sinus. Epistaxis is nose bleed or hemorrhage from the nose.

In a preferred embodiment of the present invention, the Dead Sea salt solution comprises about 5.0 to about 50.0 grams per liter of sterile aqueous solution. Said aqueous solution may be or include a buffer, water, or any other pharmacologically acceptable aqueous mixture. The buffer is to maintain the pH between about 6.5 and 7.5. A buffer is Sodium Phosphate, Potassium Phosphate, Sodium Carbonate, or such other as would be used by those skilled in the art to maintain the pH between 6.5 and 7.5. The composition of the Dead Sea salt mixture includes about 31-35% magnesium halide, about 24-26% potassium halide, about 4-8% sodium halide, about 0.4-0.6% calcium halide. The halide are preferably about 0.3 -0.6% bromide, 99.4- 99.7% chloride, and the mixture may also include about 0.05-0.2% sulphates, about 0.5-0.2% insolubles, the later of which are preferably removed by filtrates. The salts may comprise about 34-38% water of crystallization. The formulation is essentially free of noxious organic impurities, such as human waste, dead marine animals, and fossil fuel spillage. "Essentially Free" is defined as no more than harmless, trace quantities.

Although the preferred embodiment of this invention is the use of Dead Sea salt from the Dead Sea, it is understood that one skilled in the art would be able to artificially create a Dead Sea salt. It is also apparent to anyone skilled in the art, that certain pharmacologically accepted ingredients normally found in nasal spray could be added to the

SUBSTITUTE 8

CLAIMS:

1. A nasal spray formulation comprising:

a Dead Sea salt and mineral composition in aqueous solution.

2. The formulation of claim 1 where the aqueous solution is sterile.

3. The formulation of claim 1 defined further as containing a buffer.

4. The formulation of claim 3 where the buffer is to maintain a pH of from about 6.5 to about 7.5.

5. The formulation of claim 1 where the composition is from about 5.0 to about 50.0 grams per liter of aqueous solution.

6. The formulation of claim 1 where the composition is about 25.0 grams per liter of aqueous solution.

7. The formulation of claim 1 where the composition is essentially free of noxious organic impurities.

SUBSTITUTE 9

8. The formulation of claim 1 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% (wt/wt) magnesium halide, about 24-26% (wt/wt) potassium halide, about 4-8% (wt/wt) sodium halide, about 0.4-0.6% (wt/wt) calcium halide, the halide being about 0.3 -0.6% (wt/wt) bromide and about 99.4-99.7% (wt/wt) chloride.

9. A method of treating symptoms of adverse conditions affecting the nasal cavity and passageway, the method comprising the steps of identifying patient with an adverse nasal cavity conditions;

a. obtaining a premixed formulation containing a Dead Sea salt and mineral composition in aqueous solution; and

b. administering an aerosol formed from the formulation at least 1 time a day as symptoms of the patient persist.

10. The method of claim 9 wherein said conditions include rhinitis, sinusitis, epistaxis and post-surgical irritation.

11. The method of claim 9 wherein said Dead Sea salt and mineral composition is in sterile aqueous solution.

12. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution contains a buffer.

13. The method of claim 12 wherein the buffer is to maintain a pH from about 6.5 to about 7.5.

14. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution is from about 5.0 to about 50.0 grams of salt per liter of said aqueous solution.

15. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution is about 12.0 grams of salt per 480 cc of said aqueous solution.

16. The method of claim 9 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% (wt/wt) magnesium halide, about 24-26% (wt/wt) potassium halide, about 4-8% (wt/wt) sodium halide, about 0.4-0.6% (wt/wt) calcium halide, the halide being about 0.3 -0.6% (wt/wt) bromide and about 99.4-99.7% (wt/wt) chloride.

17. The method of claim 9 wherein said Dead Sea salt and mineral composition in aqueous solution is essentially free of organic impurities.

18. A method for treating symptoms of adverse conditions of the nasal cavity and passageway with a Dead Sea salt and mineral composition in aqueous solution, the method comprising the steps of obtaining a premixed formulation containing a Dead Sea salt mineral composition in aqueous solution; and self administering an aerosol formed from said formulations nasally at least 1 time a day as symptoms persist.

SUBSTITUTE 11

19. The method for claim 18 wherein said conditions include rhinitis, sinusitis, epistaxis and post-surgical irritation.

20. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution is from about 5.0 to about 50.0 grams per liter of said aqueous solution.

21. The method of claim 18 wherein a Dead Sea salt mineral composition is in sterile aqueous solution.

22. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution contains a buffer.

23. The method of claim 22 wherein the buffer is to maintain a pH of from about 6.5 to about 7.5.

24. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution is about 25.0 grams per liter of said aqueous solution.

25. The method of claim 18 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% (wt/wt) magnesium halide, about 24-26% (wt/wt) potassium halide, about 4-8% (wt/wt) sodium halide, about 0.4-0.6% (wt/wt) calcium halide, the halide being about 0.3 -0.6% (wt/wt) bromide and about 99.4-99.7% (wt/wt) chloride.

26. The method of claim 18 wherein a Dead Sea salt mineral composition in aqueous solution is essentially free of noxious, organic impurities.

27. A method of producing a nasal spray formulation comprising Dead Sea salt in aqueous solution, the method comprising dissolving Dead Sea salt in aqueous solution and storing this premixed formulation in a container suitable for aerosol nasal administration.

28. The method of claim 27 wherein a Dead Sea salt mineral composition in aqueous solution is from about 0.5 to about 5 grams per liter of said aqueous solution.

29. The method of claim 27 wherein Dead Sea salt mineral composition in aqueous solution is about 25.0 grams per liter of said aqueous solution.

30. The method of claim 27 wherein Dead Sea salt mineral composition is in sterile aqueous solution.

31. The method of claim 27 wherein Dead Sea salt mineral composition in sterile aqueous solution contains a buffer.

32. The method of claim 31 wherein the buffer is to maintain a pH of from about 6.5 to about 7.5.

SUBSTITUTE 13

33. The method of claim 27 wherein said Dead Sea salt and mineral composition is further defined as including about 31-35% (wt/wt) magnesium halide, about 24-26% (wt/wt) potassium halide, about 4-8% (wt/wt) sodium halide, about 0.4-0.6% (wt/wt) calcium halide, and halide being about 0.3 -0.6% (wt/wt) bromide and about 99.4-99.7% (wt/wt) chloride.

34. The method of claim 27 wherein a Dead Sea salt mineral composition in aqueous solution is essentially free of noxious, organic impurities.

35. A nasal spray formulation comprising a Dead Sea salt and mineral composition having about 31-35% (wt/wt) magnesium halide, about 24-26% (wt/wt) potassium halide, about 4-8% (wt/wt) sodium halide, about 0.4-0.6% (wt/wt) calcium halide, the halide being about 0.3 -0.6% (wt/wt) bromide and about 99.4-99.7% (wt/wt) chloride, where said Dead Sea salt and mineral composition contains a buffer maintaining a pH from about 6.5 to 7.5 and is from about 5.0 to about 50.0 grams per liter of sterile aqueous solution and is essentially free of noxious, organic impurities.